

FIELD NOTES

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MLT licensing coming in California?

The Machado legislation (SB 1809) in 2002 required the Department to license Medical Laboratory Technicians (MLT) by adopting regulations that set licensing standards. These regulations have been developed with the help of the CLTAC, community colleges and others, and are under review at this time. Lab Field Services has requested emergency filing and hopes the standards will be enacted soon in 2004.

The MLT regulations require an applicant to have 90 semester hours of college courses including 36 hours of science, and six months training as an MLT. There are several avenues for training including a NAACLS-approved program, an LFS-approved program, and on-the-job experience as an MLT outside California. The applicant must pass an MLT certifying examination approved by LFS and apply for licensure.

Once licensed, an MLT in California can perform all waived and moderate-complexity testing in chemistry, immunology, hematology or microbiology, but not microscopic procedures. They must be supervised by a licensed Clinical Laboratory Scientist or other baccalaureate-level person or higher, and must have 12 hours of continuing education each year.

People are asking when licensing will be available. The regulations are under review at this time, and when everything meets strict administrative standards, they can be enacted. In the meantime, we are asking your patience!

LFS Mailing Address

1111 Broadway, 19th Floor
Oakland, CA 94607
Tel.: (510) 873-6328



Continuing Education

Senate Bill 165 (Machado) which is currently working its way through the legislature, would make important changes to the current continuing education (CE) requirements in California. This bill would amend BPC 1275 to allow 12 hours of CE to be earned in a 12-month period or 24 hours in 24 months. If this law passes, then LFS can start offering staggered two-year licenses.

On the subject of continuing education, 190 approved accrediting agencies (AA) for 2003 are now available on the Internet. The list has all the information relating to contact persons, telephone numbers and/or email addresses. Many agencies now have Internet courses which make it easy to obtain the required CE hours at home.

Inactive Status

The law allows you to go on inactive status for up to five years provided you obtain 12 contact hours of CE from an approved accrediting agency in the fourth year and pay all the back fees.

You can apply for a CE waiver if:

1. You live outside of US for six or more months.
2. You are sick or taking care of sick family member for six or more months.
3. You are working outside California for six or more months on military duty.

Remember, if the license expiration exceeds the fifth year, re-examination will be required.

New License Categories

The licensing of newly regulated clinical laboratory specialists in genetic specialty areas began on an emergency basis on March 13, 2003. The titles of these new license categories are "Clinical Cytogeneticist Scientist" and "Clinical Genetic Molecular Biologist Scientist". These two new high complexity testing license categories augment two director level categories of "Clinical Cytogeneticist" and "Clinical Genetic Molecular Biologist" that were adapted by regulation in 2000.

The genetic scientists perform prenatal and postnatal genetic testing for diagnosis of inherited or acquired genetic disorders. The Margolin legislation, AB 2057 of 1993, is the basis for these emergency regulations, and at Business and Professions Code 1261.5 specifically required these categories to have a baccalaureate degree with specific

courses in the sciences. This prevented the Department of Health Services from adopting grand-fathering provisions for persons that had achieved national board certification by examination prior to 1992 without holding a baccalaureate degree.

The addition of these new categories of clinical laboratory personnel were necessary because of the emergency of Clinical genetic testing as part of clinical Laboratory scientist and an acute labor shortage of qualified Clinical Laboratory Scientists. The technologies for these categories transferred from academic research systems to Universities and Children's Hospitals and are now performed in all types of laboratories. Without qualified licensed personnel to

competently perform genetic diagnostic testing, clinical laboratories have been faced with the crisis of not performing this testing or sending the tests out-of-state. Public expectations require that laboratories provide accurate and reliable results in a timely manner. Persons have been working in California for many years using genetic testing techniques and they have been anticipating implementation of licensing regulations. It is expected that the LFS- Personnel Licensing Section will license over 400 persons in these categories by the end of 2003.

Training Schools - Update

The shortage of licensed laboratory personnel in the State of California in recent years has sent a clear and loud message to the administrators

and education coordinators throughout the state to reshuffle their priorities and put the need to start and or restart training programs in high gear. The Department has approved many new programs to train both the clinical laboratory scientists level and the limited scientist categories and also have noticed a significant expansion of existing training programs by recruiting new clinical laboratories affiliates. The diligent work of the education coordinators has contributed to an increase in the number of qualified students showing interest in pursuing careers in the laboratory sciences. Laboratory Field Services is encouraged and pleased with this trend. Thanks to all of you who contributed boundless energy and time in keeping this momentum to preserve our profession and continuously moving it forward.

Phlebotomy Program

There are 3 new categories of phlebotomists. Every phlebotomist must obtain one of the following state certificate: Limited Phlebotomy Technician; Certified Phlebotomy Technician 1; Certified Phlebotomy Technician 2. **Experienced Phlebotomists** – those with either paid or volunteer on-the-job-experience (OTJE) acquired between 4-9-9 to 4-9-03 will have until 4-9-06 to obtain a state certificate (3- year grace period/ "grandfather clause"). To obtain a state certificate, the

A FEW SIMPLE RULES



- Get 12 contact hours from the accrediting agencies approved by the LFS.
- Make sure you get a proper certificate with accrediting agencies number and course number.
- You must report your continuing education to LFS, not the provider.
- Report all address changes to LFS within 30 days.
- Keep your certificates with your other legal documents for four years.
- Sign your CE personnel license form.
- Respond to any audit notice.

phlebotomist must satisfy 5 requirements: 1) submit a transcript or documentation directly from the school to LFS that verifies high school (HS) graduation or college coursework or having passed the General Education Development (GED) examination, 2) obtain signed documentation from an employer of OTJE acquired between 4-9-98 to 4-9-03 which verifies at least 25 capillary punctures (LPT) or 50 venipunctures and 10 capillary punctures (CPT 1) or 50 venipunctures, 10 capillary and 20 arterial punctures (CPT 2), 3) complete 20 or 40 hours of classroom instruction from a state approved training program, 4) pass a written examination given by a state approved certifying organization (except LPTs), and 5) submit a completed state application to LFS with documentation of items 1-5 above, 2 passport size photographs and a \$54 fee.

“New Phlebotomists” – must satisfy 4 requirements: 1) graduate from HS, pass the GED or pass the High School Proficiency Examination, 2) complete classroom and practical/clinical externship instruction from an approved training program as an: LPT – 20 hours classroom instruction and clinical externship performing 25 capillary punctures; CPT 1 – at least 40 hours basic/advanced classroom instruction and 40 hours clinical externship performing 50 venipunctures and 10 capillary punctures; or CPT 2 – complete the CPT 1 coursework, acquire 6 months OTJE, and complete practical training performing 25 arterial punctures, 3) pass a written examination from an approved certifying organization, 4) submit a completed state application to LFS with documentation of items 1-3 above, 2 passport size photographs and a \$54 fee.

All Phlebotomists – must satisfy 2 requirements: 1) complete 3 Continuing Education (CE) hours per year/6 CE hours for 2 years from an approved CA state CLS CE Accrediting Agency, -2) renew the state certificate every 2 years with a \$54 fee and documentation verifying completion of 6 CE hours.

Hiring – 2 types of phlebotomists can be hired: 1) those who were trained/certified under the old laws and acquired OTJE prior to 4-9-03 - these individuals need not obtain a state certificate until 4-9-06, 2) “new phlebotomists” without prior OTJE or training as of 4-9-03 – these individuals must obtain the state certificate before they seek employment.

More Questions ? Contact Gwen Wong
: g w o n g 2 @ d h s . c a . g o v

Cytotechnologist. This is the only program in LFS that repeats tests run by the laboratory. Currently there are three Cytotechnologists working in the program. Cytotechnologists working in California may not screen more than 80 gynecological slides a day. There is proposed legislation that would allow cytotechnologists to screen 100 thin preparation slides a day (SB 1077, introduced by the Senate Committee on Business and Professions.)

Rapid HIV Antibody Testing

Does your laboratory plan to offer rapid HIV antibody testing? If yes, make sure your laboratory obtains state approval prior to testing and reporting patient results. California Code of Regulations, Title 17, Section 1230, which was adopted in 1985, requires clinical laboratories to file application to perform HIV antibody tests. Currently approved laboratories will still need to obtain additional approval for the performance of any rapid HIV antibody test, regardless of the CLIA complexity of the test system. One of the requirements of the California HIV regulations is that laboratories are to follow manufacturer’s instructions strictly. No modification to the test system is allowed.


More questions? Contact Shiu-Land Kwong at 510-873-6405.

The Public Health

Since 1923, the California Health and Safety Code has mandated that the county and municipal (local) public health laboratories and their personnel be approved by the State Department of Health. The public health laboratory program provides those approvals. Functioning as a mini-LFS within LFS, the program includes many of the diverse activities performed by separate LFS programs. Broadly, these are the state and federal on-site laboratory inspection activities and the personnel certification activities. The certification of public health microbiologists includes the approval of trainees, the approval of training programs, and the development and administration of the certifying examination. The program oversees 38 county/city public health laboratories and has certified 1918 public health microbiologists. The program also develops regulations, interacts with other governmental agencies and is a reference for the laboratory community on public health laboratory issues such as the blood lead testing programs, the non-diagnostic health assessment programs, the laboratory reportable disease requirements.

CLIA Update

The CDC and CMS published in the Federal Register on January 24, 2003, a final rule entitled “Medicare, Medicaid and CLIA Programs; Laboratory Requirements relating to Quality Systems and Certain Personnel Qualifications”. This regulation contains a restructuring of former subparts J (Patient Test



Cytology

The cytology program is responsible for the licensure of the state’s cytotechnologists and the special surveys of California’s licensed laboratories that provide cytology services. There are approximately 775 active cytotechnologists and 438 clinical laboratories screening about 7 million gynecological slides and one million non-gynecological slides a year. These laboratories are assessed a fee based on the number of slides read. The program conducts special surveys conducted by the Departments

Management), K (Quality Control) (Q.C.) and P (Quality Assurance) into two new subparts. J – Facility Administration for non-waived testing, and K – Quality Systems for non-waived testing. However, many of the requirements remain the same. This reorganization allows the regulatory requirements to follow the path of patient specimens through the laboratory, i.e. specimen receiving, testing and result reporting. In addition, the regulation reduces Q.C. frequency in many of the specialties and subspecialties, eliminates redundancy, clarifies requirements, uses plain language where possible, and offers flexibility in complying with the Q.C. requirements. The final rule completes the phase in provisions, provide one set of Q.C. requirements for non waived testing, removes the prospective FDA review of manufacturer's Q.C. instructions for compliance with CLIA that was to occur after the end of the Q.C. phase-in, and "grandfathers" individuals with a doctoral degree without board certification and have served or is currently serving as a High Complexity Laboratory Director and requires board certification for all future doctoral degree directors of high complexity laboratory testing. The Ph.D. requirement became effective February 24, 2003, all other requirements April 24, 2003. CMS will provide training for the Examiners in San Francisco on September 22-26, 2003. At that time the surveyors will also be trained on the use of the new Interpretive Guidelines. The Interpretive Guidelines will be available to the general laboratory community at a later date.

Donna McCallum, Section Chief, CLIA

Staff of Personnel Licensing Department



Field Notes

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Editor: Shahrzad Radahd

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Few tips about the Law

Facility Licensing section has several sections of California law that have been of interest lately.

California Business and Professions Code (BPC) Section 1265 (b) and (g) states owners and directors of any laboratory are jointly responsible for the conduct of the lab and compliance and Directors are held responsible until they notify LFS in writing that they have resigned. The effective date of the resignation is the date the original, signed document is received by LFS. After a major change (>50%) of ownership or director, the laboratory license is forfeited after 30 days. To remain in compliance and continue to perform testing, the laboratory must notify LFS of the change and file a complete application with LFS within 30 days for a new laboratory license. If the sole laboratory director resigns, the laboratory must appoint a new interim director within 5 days.

BPC Section 1209 (f) requires that all laboratory directors of an acute care hospital be pathologists, unless the separate laboratory only performs blood gas analysis and electrolytes. In this case the respiratory laboratory under the direction of a physician who is not a pathologist may only do these limited tests.

CONTACTS

Gwen Wong, (Phlebotomy)	(510) 873-6449
Frank Barnes (Training school)	(510) 873-6348
Joseph Musallam (CLS licensing)	(510) 873-6352
Shahrzad Radahd (CE)	(510) 873-6354

FAQS

Q What is the contact for laboratories that wish technical assistance about the Health Insurance Portability and Accountability Act (HIPAA)?

A US Dept. of Health and Human Services

Office for Civil Rights,

1-800-627-7748

Web site: www.hhs.gov/ocr/hipaa

Q If an individual does not have "CE" hrs in previous year, is it OK to get required hrs in the current year?

A. No

Q How do I know which organization is approved for "CE"?

A. Check on www.dhs.ca.gov/ps/ls/lfsb/html/ce_list.htm or call (510) 872-6328